

MLN Matters Number: MM6138 Revised Related Change Request (CR) #: 6138

Related CR Release Date: July 25, 2008 Effective Date: March 19, 2008

Related CR Transmittal #: R1562CP and R90NCD | Implementation Date: August 25, 2008

Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management

Note: This article is superseded by MM6313 as CR6313 replaced CR6138, on which this article had been based. CR6313 reflects additional ICD-9-CM codes involved with this issue. Those codes were inadvertently omitted from CR6138. Please see MLN Matters article MM6313, instead of using this article. MM6313 is available at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6313.pdf on the CMS website.

Provider Types Affected

Physicians, providers and suppliers submitting claims to Medicare contractors (carriers, fiscal intermediaries (FIs) or Part A/B Medicare Administrative Contractors (A/B MACs)) for home PT and International Normalized Ratio (INR) anticoagulation management monitoring services provided to Medicare beneficiaries.

Impact on Providers

This article is based on Change Request (CR) 6138, and alerts providers that effective for claims with dates of service on and after March 19, 2008 the Centers for Medicare & Medicaid Services (CMS) revised its National Coverage Determination (NCD) limits and will expand the population eligible for home coverage of PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. See the *Key Points* section of this article for details.

Background

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The prothrombin time (PT) test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the International Normalized Ratio (INR), are the standard measurements for therapeutic effectiveness of warfarin therapy. Warfarin, Coumadin®, and others, are self-administered, oral anticoagulant, or blood thinner, medications that affect a person's Vitamin K-dependent clotting factors.

Currently, Medicare's national coverage determination (NCD) at 190.11 of the NCD Manual limits coverage of home PT/INR monitoring to anticoagulation management for patients with mechanical heart valves who are on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a) (See

<u>http://www.cms.hhs.gov/ClinicalLabFeeSched/downloads/410_32.pdf</u> on the CMS website.) and the following requirements must be met:

- 1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device:
- 2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
- 3. Self-testing with the device should not occur more frequently than once a week.

CMS received a formal, complete, written request for reconsideration to expand the population eligible for coverage of home PT/INR monitoring to patients on warfarin. CR6138 is a result of that request.

Key Points

See MLN Matters article MM6313 at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6313.pdf for complete details.

Additional Information

If you have questions, please contact your Medicare A/B MAC, FI or carrier at their toll-free number which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.

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